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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,570	05/23/2000	Francois Arminjon	MBHIB00-210	9141

7590

09/27/2002

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EXAMINER

BROWN, STACY S

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 09/27/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,570

Applicant(s)

ARMINJON ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 2, 2002 has been entered.

2. Claims 21-38 are pending and examined.

Response to Arguments

3. The advisory action of May 15, 2002 indicated that claims 36 and 37 were unclear because an "effective amount" did not adequately describe the metes and bounds of the claims. However, in view of Applicant's persuasive arguments, the meaning of an "effective amount" is defined clearly in the specification.

4. Claims 21-38 remain rejected under 35 U.S.C. 103(a) as obvious over Petre *et al.* in view of Arminjon *et al.*, both of record. Applicant's arguments have been carefully considered.

Applicant mainly argues that:

- Arminjon fails to teach the elements of the claimed method:
 - (a) Adsorption of tetanus and diphtheria toxoids onto aluminum salt prior to being mixed with other components
 - (b) Preparation of conjugate in phosphate buffer solution prior to being mixed with other components

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- (c) Utilization of purified pertussis toxoid
- (d) Utilization of purified filamentous hemagglutinin
- (e) Utilization of inactivated poliovirus

- In response, the Arminjon reference is withdrawn as a primary reference for failing to disclose the elements of (a) and (b).

- Petre does not suggest (a) and (b), and the subsequent mixing with other components.

- In response, the Office notes that (a) is clearly taught in Example 2. Step (b) is not disclosed, however one of ordinary skill in the art would have known how to prepare HiB conjugate in phosphate buffer. Example 2 teaches the adsorption of tetanus and diphtheria toxoids onto aluminum salt prior to being mixed with other components.

- Petre teaches away from the use of aluminum hydroxide HbsAg in combination with other vaccine components.

- In response, the Office agrees that the use of AH absorbed HBsAg is discouraged in combination with other vaccine components. *However, the instant claims do not limit the aluminum salt to AH, but also include AP, which is taught by Petre.*

The teachings of Petre have been made of record. Petre fails to disclose some of the specific amounts of particular vaccine components. However, Arminjon discloses the amounts of components claimed by Applicant (of record). It would have been obvious to incorporate the amounts of antigens into the multivalent vaccine of Petre, as taught by Arminjon. One would

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have been motivated to use Arminjon's antigen quantities because both Arminjon and Petre make multivalent vaccines using the same components. Given the similar nature of their vaccines and the widely distributed existing multivalent vaccine containing the PRP-T antigens, one would have had a reasonable expectation of success that the amounts used by Arminjon and Petre would result in effective amounts for vaccination.

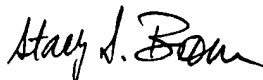
Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

5. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown
September 26, 2002



HANKYEL T. PARK, PH.D
PRIMARY EXAMINER